

79630-1

6/26/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Lewis & Harrison, LLC Consultant for K2 Concepts INC.
122 C Street, N.W., Suite 505
Washington, District of Columbia 20001

Attention: Karen E. Warkentien

JUN 26 2013

Subject: Aquastat-HU
EPA Reg. No. 79630-1
Notification Letter Dated May 28, 2013

This letter acknowledges receipt of the Notification identified above submitted under the provisions of section 3(c)(9) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10. This Notification requests to add the following marketing claims:

- Kills up to 99% of odor-causing bacteria
- Continually inhibits the growth of up to 99% of odor-causing bacteria, unsightly mold and algae on humidifier surfaces
- Inhibits the growth of up to 99% of odor-causing bacteria, unsightly mold and algae keeping your humidifier cleaner, longer
- Reduces up to 99% of odor-causing bacteria, unsightly mold and algae growth versus untreated humidified surfaces

Based on a review of the submitted information, this notification is acceptable.

Should you have any questions concerning this letter, please contact Elizabeth Hernandez at (703) 347-0241.

Sincerely,

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510P)



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 79630-1		2. EPA Product Manager Marshall Swindell		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) Aquastat(R)-HU		PM# 33			
5. Name and Address of Applicant (Include ZIP Code) K2 Concepts Inc. 114 North Prince Street, 3rd Floor Lancaster PA 17603 <input type="checkbox"/> Check if this is a new address			6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____		

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Label Change per PR Notice 98-10*****

This notification is consistent with the guidance in PR Notice 98-10 and the requirements of EPA's regulations at 40 CFR § 156.46, and no other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 USC § 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR § 156.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:						2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>Cardboard</u>	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container			4. Size(s) Retail Container 0.035, 0.21, 0.28, 0.35 oz		5. Location of Label Directions <input checked="" type="checkbox"/> on label accompanying product		
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input checked="" type="checkbox"/> Other <u>Direct printing onto cardboard cor</u>			

Section - IV

7. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Karen E. Warkentien	Title Consultant to K2 Concepts Inc.	Telephone No. (Include Area Code) (202) 393-3903 x22
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Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

8. Signature 		3. Title Consultant to K2 Concepts Inc.		6. Date Application Received (Stamped)
9. Typed Name Karen E. Warkentien		5. Date 28 May 2013		

LEWIS & HARRISON

122 C Street, N.W., Suite 505
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

Consultants in Government Affairs

28 May 2013

Via Hand Delivery

Mr. Marshall Swindell, PM #33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs
US Environmental Protection Agency
One Potomac Yard
2777 Crystal Drive
Arlington VA 22202



**SUBJECT: Aquastat HU, EPA Reg. No. 79630-1
Application for Pesticide Notification
Addition of Additional Non-Public Health Claims per PRN 98-10**

Dear Ms. Noble:

On behalf of our client, K2 Concepts Inc. (K2), Lewis & Harrison, LLC, submits herewith the following documents in support of a label notification for Aquastat HU, EPA Reg. No. 79630-1:

Volume I: Administrative Materials

- Application for Pesticide Notification (EPA Form 8570-1)
- Draft label (two copies, one with highlighted changes)

This submission is made pursuant to PR Notice 98-10 and makes revisions pursuant to your letter dated May 14, 2013 on K2's previous unacceptable label notification.

Notification of Label Change per PR Notice 98-10

This notification is consistent with the guidance in PR Notice 98-10 and the requirements of EPA's regulations at 40 CFR § 156.46, and no other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 USC § 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR § 156.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

This submission is NOT subject to processing under the Pesticide Registration Improvement Act (PRIA) and should be categorized as a notification.

4/10

Mr. Marshall Swindell, PM # [handwritten mark]
Page 2 of 2

Should you have any questions concerning this submission, please contact me by phone at (202) 393-3903 x22 or via email at kwarkentien@lewisharrison.com.

Sincerely,

LEWIS & HARRISON, LLC
Consultant to K2 Concepts Inc.



Karen E. Warkentien

Enclosures

cc: Bryan Kepner, K2 Concepts Inc.

AQUASTAT-HU

Microbistatic [Antimicrobial] Treatment for Residential Humidifier Units

Active Ingredient:		
Silver (metallic)		1.4%
Other ingredients		98.6%
TOTAL		100.0%

KEEP OUT OF REACH OF CHILDREN

Do not allow children to play with the AquaStat-HU cartridge

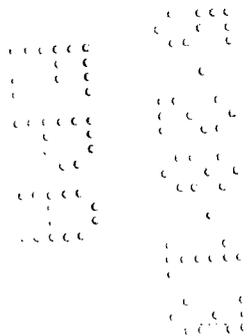
EPA Establishment No. 79630-GA-001

EPA Registration No. 79630-1

Lot/Batch Number:

Net weight each cartridge:
[one or two cartridges per package]

Manufactured for
K2 Concepts, Inc.
805 Peachtree Street NE, Suite 614
Atlanta, GA 30308



DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Remove outer package before placing cartridge into humidifier. Do not open or attempt to empty the cartridge. Retain this label for reference.

For use in the following sizes of residential humidifiers: Small portable humidifier units, Console humidifer units, Central humidifier units. For use in the following types of residential humidifiers: ultrasonic, cool mist (impeller), evaporative, steam vaporizer.

1. For every 2 gallons of water contained in the humidifier tank, use 1 AQUASTAT-HU cartridge.
2. For best results, before using for the first time, it is recommended that you clean your humidifier according to the humidifier manufacturer's instructions to remove any buildup that may have accumulated.
3. After humidifier has been cleaned, drop one (1) AQUASTAT-HU cartridge per 2 gallons of water capacity into the humidifier water reservoir and fill tank with fresh water.
4. Operate humidifier according to the manufacturer's directions and replace AQUASTAT-HU cartridge every 30 days. For deep-well reservoir tanks, shut off water and drain tank in order to retrieve the AQUASTAT-HU cartridge.

Alternate Wording for 1 gram (0.035 oz) cartridges for very small units (≤500 ml capacity):

For Units with Capacity of ≤500 ml:

1. For every 500 ml (17 fl oz) of water contained in the humidifier tank, use 1 AQUASTAT-HU cartridge.
2. For best results, before using for the first time, it is recommended that you clean your humidifier according to the humidifier manufacturer's instructions to remove any buildup that may have accumulated.
3. After humidifier has been cleaned, drop one (1) AQUASTAT-HU cartridge per 500 ml (17 fl oz) of water capacity into the humidifier water reservoir and fill tank with fresh water.
4. Operate humidifier according to the manufacturer's directions and replace AQUASTAT-HU cartridge every 30 days. For deep-well reservoir tanks, shut off water and drain tank in order to retrieve the AQUASTAT-HU cartridge.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.
Nonrefillable container. Do not reuse or refill this container.

Pesticide Storage: Do not store in areas accessible to children. Keep product dry during storage.

Pesticide Disposal: Do not reuse empty cartridge. Securely wrap cartridge in several layers of newspaper and discard in trash.

Container Disposal: Securely wrap outer carton in several layers of newspaper and discard in trash or offer for recycling, if available.

Notice: Customer is responsible for ensuring compliance with applicable laws and regulations. Any use of this product for purposes other than what is intended is strictly prohibited. Results may vary according to water quality.

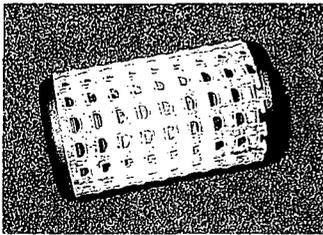
[Optional] Description of Cartridge [no more than one of these will appear on the printed label, but either/neither may be used]

Type 1: Cylinder

Cylinder composed of 100% polypropylene, with caps of 100% LDPE.

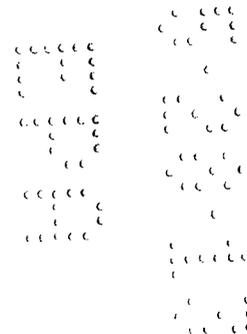
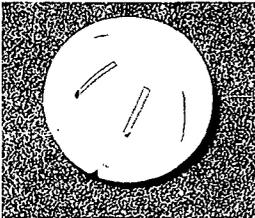
Dimensions: 2 inches (L) x 1.25" (D)

Dimensions for smaller size units (\leq 500 ml capacity): 12 mm (L) x 8 mm (D)



Type 2: Sphere

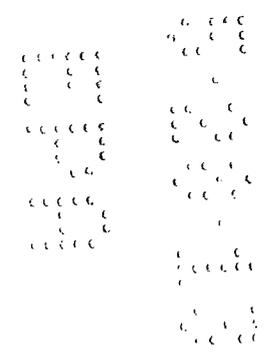
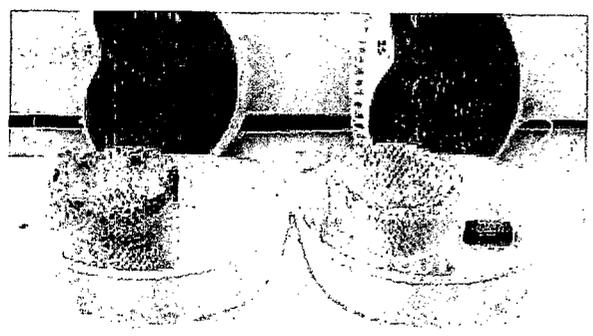
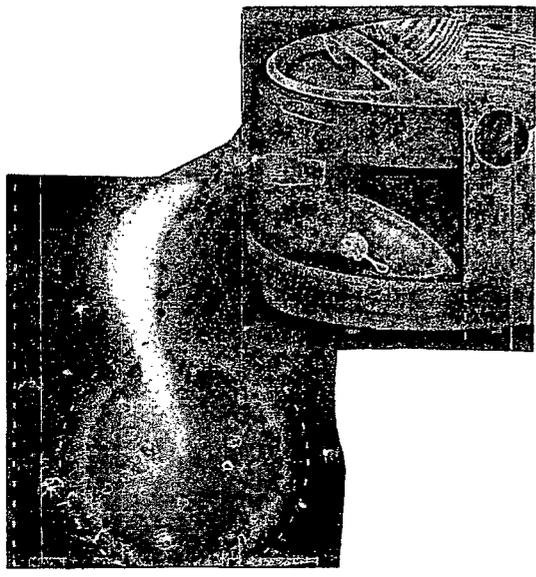
Sphere composed of 100% polystyrene. Dimensions: 30 mm (D)



Optional Marketing Statements:

- Kills bacteria [microorganisms] that cause unpleasant odors
- [Controls] [continually inhibits] [[prevents] growth [and buildup] of bacteria, mold and algae in the water tank
- [Controls] [continually inhibits] [prevents] growth of [bacteria] [mold] and [algae] [microorganisms] in the mist of cool-mist humidifiers [vaporizers] during the life of the cartridge.
- Prevents the growth of bacteria, mold and algae in the water and on the inside of the humidifier [vaporizer] tank
- Prevents the buildup of slime on the inside of the humidifier [vaporizer] tank
- Improves humidifier [vaporizer] performance by eliminating [preventing] [controlling] slime-causing microorganisms [bacteria] [mold] [algae]
- Extends the life of the humidifier [vaporizer] by eliminating [preventing] [controlling] slime-causing microorganisms [bacteria] [mold] [algae]
- Extends the life of the humidifier [vaporizer] filter/components [wick] by eliminating [preventing] [controlling] slime-causing microorganisms [bacteria] [mold] [algae]
- Provides fresh mist
- Provides both continuous cleaning and protection against odor [slime] causing [microorganisms] [bacteria] [mold] [fungi] [algae]
- Continuously cleans and protects humidifiers [vaporizers] against [bacteria] [mold] [algae]
- Keeps working [cleaning] for 30 days
- Simply drop in tank for fresh, clean mist
- Your humidifier [vaporizer] stays cleaner, longer
- You can actually see the difference!
- Continuously works to control [prevent] [inhibit] growth of [bacteria] [mold] [slime] [buildup of slime] in the water and humidifier [vaporizer] surfaces
- Uses the same antimicrobial that has been used for years in drinking water filters to prevent objectionable odors, tastes and colors
- Works in all residential humidifiers [vaporizers]
- Continuous protection against slimy build-up in humidifier [vaporizer]
- [Gentle][mild] cleaning action for your humidifier
- [Contains] no [harsh][harmful][lingering][cleaning] chemicals
- Contains no [abrasives] or [harsh acids]
- Leaves no [harsh] [harmful][lingering][corrosive] residues
- Non-[corrosive][corroding]
- [Will not harm][Non-harmful] to [metal][plastic][humidifier] components
- Just as [gentle][mild] as [soap] [and] [water] to humidifier surfaces and components
- Kills up to 99% of odor-causing bacteria
- Continually inhibits the growth of up to 99% of odor-causing bacteria, unsightly mold and algae on humidifier surfaces
- Inhibits the growth of up to 99% of odor-causing bacteria, unsightly mold and algae keeping your humidifier cleaner, longer
- Reduces up to 99% of odor-causing bacteria, unsightly mold and algae growth versus untreated humidifier surfaces)

[The Following Two Optional graphics]



Optional Marketing Graphic

Virtually no odor and slime causing bacteria found in humidifier using Aquastat HU

